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United States Court of Appeals
Tenth Circuit

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Elisabeth A. Shumaker
Clerk of Court

UNITED STATES COURT OF APPEALS

TENTH CIRCUIT

HOPE HUERTA, as Next Friend and Parent of Blanca M. Valdez-Huerta, a minor,

Plaintiff-Appellant,

v.

BIOSCRIP PHARMACY SERVICES, INC.,

Defendants-Appellees.

No. 10-2203
(D.C. No. 1:09-CV-00485-RHS-LFG)
(D. N.M.)

ORDER AND JUDGMENT[*]

Before **O'BRIEN, HOLLOWAY**, and **GORSUCH**, Circuit Judges.

Following a catastrophic rejection of her transplanted kidney in May of 2006, plaintiff-appellant Blanca Valdez-Huerta, by and through her mother, Hope Huerta, (collectively, "Huerta"), brought this diversity jurisdiction action against BioScrip Pharmacy Services, Inc. ("BioScrip") in the District of New Mexico. Huerta asserted claims under New Mexico law for strict products liability, negligence, negligent

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[*] This order and judgment is not binding precedent, except under the doctrines of law of the case, res judicata, and collateral estoppel. This court generally disfavors the citation of orders and judgments; nevertheless, an order and judgment may be cited under the terms and conditions of 10th Cir. R. 36.3.

misrepresentation, deceptive trade practices, breach of express and implied warranties, and punitive damages. All of Huerta's claims were premised on the theory that BioScrip dispensed subpotent tacrolimus[1] to her, eventually resulting in her kidney rejection.

The district court[2] granted summary judgment in favor of BioScrip after striking Huerta's experts' testimony on causation. Final judgment was entered on August 19, 2010 and Huerta timely filed her notice of appeal. We have jurisdiction pursuant to Title 28, United States Code, Section 1291. For the reasons stated below, we AFFIRM.

I. Facts

A. Huerta's Kidney Transplant and Rejection

In August of 2003, Huerta, seven years old at the time, received a kidney transplant. As part of her medication regime, she took immunosuppressants, including tacrolimus and Cellcept, to help prevent her body from rejecting the transplanted kidney. In February of 2006, Huerta was hospitalized after she suffered a series of pneumonias

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[1] Tacrolimus is an immunosuppressant that was prescribed to Blanca to prevent her body from rejecting the kidney transplant. A body's immune system normally attacks foreign tissues, including transplants, resulting in the body's rejecting the organ transplant. Paul S. Russell, M.D., *Transplantation*, *in* THE MERCK MANUAL OF MEDICAL INFORMATION 1076 (2d ed. 2003). Immunosuppressants can usually control rejections by suppressing the immune system and therefore the body's ability to recognize and destroy foreign substances, such as transplant tissue. *Id.* Potency refers to the amount of a drug needed to produce an effect. G. Victor Rossi, PhD, *Drug Dynamics*, *in* THE MERCK MANUAL, *supra*, at 73. "Subpotent tacrolimus" thus refers to a preparation of tacrolimus that contained less than the prescribed amount of tacrolimus.

[2] The parties consented to Magistrate Judge Robert Hayes Scott's serving as the presiding judge and entering final judgment in this action pursuant to Title 28, United States Code, Section 636(c) and Federal Rule of Civil Procedure 73(b). Accordingly, the references in this order to the "district court" refer to Magistrate Judge Scott.

that did not clear with antibiotics. On March 8, 2006, Huerta's treating nephrologists replaced Cellcept with a weaker immunosuppressant, Imuran, because they believed that Cellcept over-suppressed her immune system and may have increased her risk of infection. Huerta continued to take tacrolimus.

On May 15, 2006, Huerta was admitted to the University of New Mexico Hospital (UNMH) after she had been vomiting for three nights. Physicians at UNMH determined that Huerta was suffering an acute, severe, and sudden rejection of her kidney transplant. Dr. John Brandt, one of Huerta's treating nephrologists, reduced Huerta's tacrolimus dosage on May 15 because he was concerned that she might have too much tacrolimus in her system. Huerta's tacrolimus level on May 15th was not measured and the experts appear to agree that without a measurement, there is no way to know what Huerta's tacrolimus level was on that day. On May 17, 2006, lab reports showed that Huerta's tacrolimus level was 2.5. Before Huerta's kidney rejection, her last tacrolimus level was measured at 5.4 on April 12, which is apparently considered normal.

Huerta partially recovered from the May 2006 rejection episode but suffered another rejection episode in May 2007. The treatment notes from Huerta's May 2007 rejection episode showed that "she had undetectable levels" of tacrolimus and her doctors were concerned "that her mother wasn't dosing her properly." Mem. Order and Op. Granting BioScrip's Motion to Exclude Proposed Testimony of Doctors Craig Wong, Bruce Morgenstern, and Loyd Alexander, August 13, 2010 ("Aug. 13, 2010 Op.") at 8 & nn. 6 & 7. Only Huerta's 2006 rejection is at issue in this case.

Just prior to Huerta's 2006 kidney rejection, a distributor of tacrolimus issued a recall for its tacrolimus which was found to be subpotent. It is undisputed that the BioScrip tacrolimus was not subject to the recall.

B. BioScrip's Tacrolimus Suspension

Huerta had her tacrolimus prescription filled by BioScrip in April of 2006. BioScrip had compounded, or mixed, the liquid form of tacrolimus (called a "suspension") by crushing tacrolimus capsules and mixing the resulting powder with a syrup according to recipes in the National Children's Hospital Pharmacy Guide. The tacrolimus capsules were manufactured and distributed by Astellas Pharma U.S., Inc., a party dismissed from the instant case because there was no evidence that the tacrolimus Astellas manufactured and supplied to BioScrip was subpotent or had been the subject of a recall.

BioScrip filled Huerta's tacrolimus prescription from its Batch No. 37. Three other individuals also had their prescriptions filled from Batch No. 37. BioScrip did not receive any reports of error or of adverse reactions from those other three individuals.

C. Proceedings Below

Both parties filed *Daubert*[3] motions to exclude the other party's expert testimony. After the district court granted BioScrip's motions and denied Huerta's motions, BioScrip moved for summary judgment on all claims. The district court granted BioScrip's motion, finding that without her experts, Huerta could not establish to a reasonable degree

[3] *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993).

of medical probability that BioScrip's tacrolimus suspension was subpotent or that it caused her kidney rejection.

II. Discussion

A. Huerta's Expert Witnesses

The Supreme Court has explained that when a trial court is "[f]aced with a proffer of expert scientific testimony . . . the trial judge must determine at the outset . . . whether the expert is proposing to testify to (1) scientific knowledge that (2) will assist the trier of fact to understand or determine a fact in issue." *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 589-93 (1993) (citing Fed. R. Evid. 104(a), footnotes omitted). Accordingly, the district court must "[first] determine if the expert's proffered testimony . . . has 'a reliable basis in the knowledge and experience of his [or her] discipline.'" *Norris v. Baxter Healthcare Corp.*, 397 F.3d 878, 883-884 (10th Cir. 2005) (quoting *Bitler v. A.O. Smith Corp.*, 400 F.3d 1227, 1232 (10th Cir. 2004)). "In making this determination, the district court must decide 'whether the reasoning or methodology underlying the testimony is scientifically valid.'" *Id.* at 884 (same). Next, "the district court must further inquire into whether proposed testimony is sufficiently 'relevant to the task at hand.'" *Id.* (quoting *Daubert*, 509 U.S. at 597) (footnote omitted).

The Supreme Court has articulated four non-exclusive considerations to aid in assessing the reliability of an expert's testimony: (1) whether the expert's theory can be tested or falsified; (2) whether the theory or technique has been subject to peer review and publication; (3) whether there are known or potential rates of error with regard to specific

techniques; and (4) whether the theory or approach has general acceptance. *Daubert*, 509 U.S. at 593-94. The district court must "make certain that an expert . . . employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 152 (1999).

We review a district court's decision to admit or exclude expert testimony for an abuse of discretion. *Id.* Under this deferential standard of review, we reverse a district court's decision only if it is "arbitrary, capricious, whimsical or manifestly unreasonable," or if "we are convinced that the district court made a clear error of judgment or exceeded the bounds of permissible choice in the circumstances." *Norris*, 397 F.3d at 883 (citing *Dodge v. Cotter Corp.*, 328 F.3d 1212, 1223 (10th Cir. 2003)). This standard "applies as much to the trial court's decisions about how to determine reliability as to its ultimate conclusion." *Kumho Tire*, 526 U.S. at 152; *see Goebel v. Denver and Rio Grande W. R.R. Co.*, 346 F.3d 987, 990 (10th Cir. 2003) ("The trial court's broad discretion applies both in deciding how to assess an expert's reliability, including what procedures to utilize in making that assessment, as well as in making the ultimate determination of reliability.").

1. District Court's Orders

The district court struck portions of the testimony of Huerta's four experts, Dr. Craig Wong, Dr. Steven Alexander, Dr. Bruce Morgenstern, and Dr. Randall Tackett, as unreliable and therefore inadmissible under *Daubert* and Federal Rule of Evidence 702.[4]

[4] Federal Rule of Evidence 702 provides the following:
If scientific, technical, or other specialized knowledge will assist the trier of

First, the district court held that Dr. Wong, Dr. Alexander, and Dr. Morgenstern were all "well qualified to give an opinion stating that, based on (1) the severity, (2) the type, and (3) abruptness of Blanca's rejection when she had been doing well the month before, (4) the extremely high creatinine[4] levels in her blood on May 15, 2006, and the fact that (5) tacrolimus is the most powerful and the most critical immunosuppressant medication Blanca was taking . . . Blanca's rejection was most likely caused by insufficient levels of tacrolimus and/ or other immunosuppressants in her system." Aug. 13, 2010 Op. at 10. The district court found, however, that "[w]hat [wa]s *not* supported by any medical evidence in the record . . . [is] their opinions regarding the *cause of the insufficient tacrolimus level*." *Id.* (emphasis in original).

As for Dr. Tackett, the district court held that he could testify to a potential relationship between sloppy pharmaceutical record-keeping and sloppy compounding, as well as to the most common types of compounding errors made when capsules are used to compound a suspension. However, the district court held that Dr. Tackett's ultimate

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> fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

[4] Creatinine is a metabolic waste product generated by the body. DORLAND'S ILLUSTRATED MEDICAL DICTIONARY 390 (28th ed. 1994). Normally functioning kidneys filter creatinine from the bloodstream and the body then excretes it in urine. Ralph E. Cutler, MD, *Kidney Failure*, *in* THE MERCK MANUAL, *supra* note 1, at 828. When a kidney fails and is therefore unable to filter creatinine, "[a] progressive daily rise in the creatinine indicates acute kidney failure." *Id.* at 829. "[T]he higher the level [of creatinine], the more severe the failure is likely to be." *Id.*

causation testimony that subpotent tacrolimus caused Huerta's kidney rejection was insufficiently reliable to be admissible.

Stated differently, the district court found that the experts were qualified to opine on general causation, or what might cause a kidney rejection. *See Norris*, 397 F.3d at 881 ("General causation is whether a substance is capable of causing a particular injury or condition in the general population."). However, the district court held that the experts could not render their specific causation opinions that Bioscrip's tacrolimus suspension was subpotent or that subpotent tacrolimus caused *Huerta's* kidney rejection because their methodologies were insufficiently reliable. *See id.* ("[S]pecific causation is whether a substance caused a particular individual's injury."). We address the contentions regarding each of the experts in further detail below.

2. Testimony of Dr. Craig Wong

According to Huerta, Dr. Craig Wong was prepared to testify that, to a reasonable degree of medical certainty, subpotent tacrolimus dispensed by BioScrip caused Huerta's kidney rejection. The district court, however, found that Dr. Wong's testimony was unreliable because it was not supported by any direct evidence that the BioScrip tacrolimus suspension was actually subpotent and because Dr. Wong's testimony was based on the erroneous assumption that Huerta had taken the recalled tacrolimus, which she had not. Aug. 13, 2010 Op. at 11; *see Goebel*, 346 F.3d at 991.

Insofar as Dr. Wong reached his causation opinion by rendering a "differential diagnosis," the district court also found that Dr. Wong's methodology fell short. A

"differential diagnosis" is one rendered by a physician who first "'rule[s] in' all scientifically plausible causes of the plaintiff's injury. The physician then 'rules out' the least plausible causes of injury until the most likely cause remains." *Hollander v. Sandoz Pharm. Corp.*, 289 F.3d 1193, 1209 (10th Cir. 2002) (quoting *Glasteter v. Novartis Pharm., Corp.*, 252 F.3d 986, 989 (8th Cir. 2001)). Then, "[t]he remaining cause is the expert's conclusion." *Id.* (citing same).

Our circuit has recognized that a differential diagnosis can be admissible if the district court concludes that it is reliable and if general causation has been established. *Goebel*, 346 F.3d 987 (citing *Hollander*, 89 F.3d at 1210). As the Sixth Circuit has explained, however,

> Calling something a 'differential diagnosis' . . . does not by itself answer the reliability question but prompts three more: (1) Did the expert make an accurate diagnosis of the nature of the disease? (2) Did the expert reliably rule in the possible causes of it? (3) Did the expert reliably rule out the rejected causes? If the court answers "no" to any of these questions, the court must exclude the ultimate conclusion reached.

Pluck v. BP Oil Pipeline Co., --- F.3d ----, 2011 WL 1794293, 5 (6th Cir. 2011) (citing *Tamraz v. Lincoln Elec. Co.*, 620 F.3d 665, 674 (6th Cir.2010) (*cert. denied*, --- S. Ct. ----, 2011 WL 863879 (May 16, 2011) (Nos. 10-1122, 10A744)). To that end, the district court answered "no" to the last two questions.

The district court found that Dr. Wong "ruled in" subpotent tacrolimus as a potential cause of Huerta's kidney rejection because of the severity of Huerta's rejection and the concurrent tacrolimus recall when she was hospitalized. Although Dr. Wong did

not know which manufacturer issued the recall, "he assigned a 'blanket blame on every liquid [tacrolimus] preparation.'" Aug. 13, 2010 Op. at 6 (quoting R., Vol. I at 72). Because it turned out that Huerta had not taken the recalled tacrolimus, and because there was no direct evidence of the potency of the tacrolimus suspension or of Huerta's tacrolimus levels when she was admitted to the hospital, the district court found that there was no way to "test" Dr. Wong's hypothesis that subpotent tacrolimus caused Huerta's kidney rejection. *Id.*; *see also Daubert*, 509 U.S. at 593-94.

The district court also found that Dr. Wong's testimony was based on Huerta's attorneys' erroneous representations that test results showed that the tacrolimus suspension was subpotent when such test results did not exist. Aug. 13, 2010 Op. at 6-7. When he was informed that the purported test results did not actually exist, Dr. Wong conceded that "if there [wa]s 'no evidence to show that [Bioscrip's tacrolimus suspension] was subpotent, then I don't think anybody can say what caused the rejection, and that's just history.'" *Id.* at 7 (quoting R., Vol. II at 489).

The district court also found that Dr. Wong's "ruling out" Huerta's non-compliance with her medication regime as a potential cause of her kidney rejection was wanting. It was based only on "knowing" Huerta's family, without any investigation into whether Huerta's family had properly administered her medication in the weeks before the rejection and without examining the suspension bottles to determine how much of the suspension had been used. *Id.* at 11-12.

Given these deficiencies, the district court found that Dr. Wong's opinion was "not 'supported by appropriate validation – *i.e.*, 'good grounds,' based on what is known.'" *Id.* at 11 (quoting *Daubert*, 509 U.S. at 590).

As a significant matter, we find telling Dr. Wong's concession that he would only be speculating as to the cause of Huerta's kidney rejection when it was revealed to him that there was no direct evidence measuring the potency of Huerta's tacrolimus suspension. Our court has previously stated that "[t]o be reliable under *Daubert*, an expert's scientific testimony must be based on scientific knowledge . . . and not mere 'subjective belief or unsupported speculation.'" *Goebel*, 346 F.3d at 991 (quoting *Daubert*, 509 U.S. at 590); *see Mitchell v. Gencorp Inc.*, 165 F.3d 778, 780 (10th Cir. 1999). This indicates that the district court did not abuse its discretion in excluding Dr. Wong's testimony as unreliable.

Moreover, given Dr. Wong's concession, his final testimony and the evidence and methodology upon which he relied are unclear to us. *See Mitchell*, 165 F.3d at 781 ("At a minimum, the expert testimony should include a description of the method used to arrive at the level of exposure and scientific data supporting the determination. The expert's assurance that the methodology and supporting data [are] reliable will not suffice.") (citing *Moore v. Ashland Chem., Inc.*, 151 F.3d 269, 276 (5th Cir. 1998) (en banc)). Only piecemeal excerpts of Dr. Wong's deposition testimony are provided to us, and Huerta's briefing does not articulate his final proffer. On this record, we cannot find that the

district court was manifestly unreasonable in excluding Dr. Wong's testimony as unreliable.

None of Huerta's arguments persuades us otherwise. Huerta argues that Dr. Wong's testimony was supported by his observation that her kidney rejection was one of the most severe and catastrophic rejection episodes he had seen. The district court, however, held only that Dr. Wong *could* testify that Huerta's kidney rejection was severe and catastrophic. What the district court found lacking, however, was the causal link between the severity of the rejection and the potency of BioScrip's tacrolimus suspension. And we find that the district court was within its discretion to so conclude. *See Goebel*, 346 F.3d at 992 ("'A court may conclude that there is simply too great an analytical gap between the data and the opinion proferred.'") (quoting *General Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997)).

Our court has stated that "a differential diagnosis is most useful when 'the party relying on the diagnosis has offered independently reliable evidence that the allegedly dangerous drug or substance had harmful effects.'" *Goebel*, 346 F.3d at 999 (quoting *Hollander*, 289 F.3d at 1210). Here, the evidence appears to be weak or entirely missing to show that the tacrolimus suspension administered to Huerta was subpotent. *See, e.g.*, *Nelson v. Tenn. Gas Pipeline Co.*, 243 F.3d 244, 253 (6th Cir. 2001) ("Without any factual basis from which a jury could infer that the plaintiffs were in fact exposed to PCBs from Station 79, the reasoning and methodology underlying the testimony is not scientifically valid."). Huerta's argument that her other experts' differential diagnoses

constituted "direct evidence," even though they had been excluded as unreliable, is clearly unpersuasive. Aplt's Br. 17-18.

Huerta next argues that contrary to the district court's findings, Dr. Wong properly ruled out non-compliance with the prescribed treatment as a possible cause of Huerta's kidney rejection. The district court found that Dr. Wong summarily ruled out non-compliance based only on "knowing" Huerta's family. Dr. Wong did so even though he acknowledged that Huerta's physicians were concerned that non-adherence may have led to her subsequent kidney rejection episode in May of 2007 when she was taking a different form of tacrolimus. Aug. 13, 2010 Op. at n.6. Huerta argues that Dr. Wong properly based his "ruling out" of non-adherence on his seeing non-adherence in patients "on a quite regular basis." Aplt's Br. 16 (quoting R., Vol. I at 112). Dr. Wong also testified that non-adherence would not have caused the type of rejection he saw in Huerta. *Id.* (citing same). Dr. Wong also testified that some teenagers fail to take their medicine "10 to 25 percent of the time and they still kind of manage to do okay." *Id.* (citing R., Vol. I at 120). Despite Huerta's arguments, we cannot conjecture about the viability of Dr. Wong's conclusion in view of his concession that he would be speculating as to the cause of Huerta's kidney rejection in the absence of evidence. On the record submitted to us, we are unpersuaded that the district court was unreasonable in finding that Dr. Wong did not properly rule out non-adherence as a potential cause of Huerta's kidney rejection.

Huerta next argues that the district court abused its discretion by faulting her for not providing direct evidence of the potency of the tacrolimus suspension when

insufficient tacrolimus remained for testing. To the contrary, the district court did not require direct evidence as a baseline to sustain Dr. Wong's testimony, but found that in this case, no other evidentiary link could reliably connect the tacrolimus suspension with Huerta's rejection. Aug. 13, 2010 Op. at 6-7; *see also Kumho Tire*, 526 U.S. at 153 ("[W]hether *Daubert's* specific factors are, or are not, reasonable measures of reliability in a particular case is a matter that the law grants the trial judge broad latitude to determine.") (quoting *Joiner*, 522 U.S. at 143). By conceding that he could not say what caused Huerta's kidney rejection without evidence that the tacrolimus was subpotent, Dr. Wong appears to agree with the district court's assessment. R., Vol. II at 489.

Lastly, Huerta argues that the district court mischaracterized Dr. Wong's testimony as "ruling in" subpotent tacrolimus solely on the assumption that Huerta was administered the recalled tacrolimus. However, Huerta's argument fails for two reasons. First, the district court recognized that Dr. Wong's testimony was based on both the severity of Huerta's rejection and also on the recall. Aug. 13, 2010 Op. at 6. As discussed above, the district court found that while Dr. Wong could testify to the severity of Huerta's rejection, that testimony fell short of establishing subpotent tacrolimus as a cause for Huerta's kidney rejection. Second, as to the recall, Dr. Wong testified that at the time of Huerta's 2006 hospitalization, he hypothesized that subpotent tacrolimus could have caused Huerta's kidney rejection by assigning a "blanket blame on every liquid [tacrolimus] preparation and, you know, guilty unless proven innocent." *Id.* (quoting R., Vol. I at 72). Whether Dr. Wong continued to rely on this in his final testimony given his

prior concession is unclear to us from the record, and on this we also decline to speculate. Accordingly, this last argument clearly fails.

For all the foregoing reasons, we find that the district court did not abuse its discretion in excluding Dr. Wong's testimony.

3. Testimony of Dr. Steven Alexander

Like Dr. Wong, Dr. Steven Alexander was prepared to testify that to a reasonable degree of medical certainty, the cause of Huerta's kidney rejection was inadequate immunosuppression resulting from "a preparation of [t]acrolimus that was insufficient." R., Vol. I at 130. The district court held that Dr. Alexander's testimony was unreliable because it was based on the erroneous assumption that Blanca's tacrolimus suspension was subpotent even though that had not yet been established, Aug. 13, 2010 Op. at 11; R., Vol. I at 74, and because it was not based on any known facts.

The district court found that Dr. Alexander's differential diagnosis fell short of reliability. For example, Dr. Alexander testified that almost nothing would cause Huerta's creatnine level to go from 0.6 to 9 except nonadherence. *Id.* at 80 (testifying that of the six different suspected explanations for creatinine levels spiking in kidney transplant patients when they have been stable for two years, nonadherence is considered numbers one, two, and three). Yet, Dr. Alexander ruled out "non-adherence" based on "knowing" Huerta's family. *Id.* at 87, 90. Dr. Alexander, however, was not aware that following Huerta's 2007 kidney rejection, "one of the concerns was that multiple family members were providing Blanca with her oral medications, and that they were concerned

she wasn't being dosed sufficiently." *Id.* at 88.[5]

When Dr. Alexander was informed that Huerta's treating physicians suspected non-compliance as a cause of her 2007 kidney rejection, he maintained that compliance was not an issue in the May 2006 rejection because he "ha[d] no reason to doubt that [Huerta's] mother was giving her her medications." *Id.* at 90. The district court's finding this to fall short of reliable testimony was not an abuse of discretion because Dr. Alexander did not "provide reasons for rejecting alternative hypotheses 'using scientific methods and procedures.'" *Clausen v. M/V NEW CARISSA*, 339 F.3d 1049, 1058 (9th Cir. 2003) (quoting *Claar v. Burlington N. R.R. Co.*, 29 F.3d 499, 502 (9th Cir.1994)). Dr. Alexander's ruling out of non-adherence in view of contradictory evidence should have been "founded on more than 'subjective beliefs or unsupported speculation.'" *Id.* (same). Although "'[t]rained experts commonly extrapolate from existing data[,] . . . nothing . . . requires a district court to admit opinion evidence which is connected to existing data only by the ipse dixit of the expert. '" *Mitchell*, 165 F.3d at 782 (quoting *Joiner*, 522 U.S. at 146).

[5] In her reply brief, Huerta argues for the first time that the district court could not properly consider her May 2007 rejection as evidence of whether she took her medicine as prescribed in the time leading to her May 2006 rejection. Reply Br. 13. Huerta argues that this was "wholly irrelevant, constitute[d] improper character evidence, [was] more prejudicial than probative," and was reversible error. *Id.* (citing Fed. R. Evid. 402, 403, and 404). By not raising this issue in her opening brief, however, Huerta has forfeited her right to appellate review of it. *See Bronson v. Swensen*, 500 F.3d 1099, 1104 (10th Cir. 2007) (explaining that "the omission of an issue in an opening brief generally forfeits appellate consideration of that issue").

Dr. Alexander's belief that he had no reason to doubt that Huerta was being dosed properly despite squarely contradictory evidence indicates that the district court was within its discretion to find his testimony unreliable. As our court has previously stated, "'scientists whose conviction about the ultimate conclusion of their research is so firm that they are willing to aver under oath that it is correct prior to performing the necessary validating tests [may] properly be viewed by the district court as lacking the objectivity that is the hallmark of the scientific method.'" *Id.* at 783 (quoting *Claar*, 29 F.3d at 503).

The district court also found that Dr. Alexander relied at least in part on Huerta's attorneys' representations that the tacrolimus suspension was subpotent. The district court found that this rendered his methodology unreliable because it was "derived from erroneous facts or assumptions." Aug. 13, 2010 Op. at 11. We find that the district court was acting within its discretion in excluding Dr. Alexander's testimony on this ground. *C.f. In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 762 (3d Cir. 1994) ("We do not doubt the propriety of a medical report prepared just for litigation, but a physician who evaluates a patient in preparation for litigation should seek more than a patient's self-report of symptoms or illness . . . in order to determine that a patient is ill and what illness the patient has contracted.").

Huerta argues that Dr. Alexander's testimony was based on his experience with other children who had undetectable levels of tacrolimus even though they were very compliant. Huerta also argues that Dr. Alexander based his testimony on his observations that Huerta had shown no prior problems and that her age group was the best in terms of

compliance. Moreover, Dr. Alexander also observed that improper compounding rather than improper dosing caused problems similar to those experienced by Huerta in children who took liquid tacrolimus. Even taking all of these observations as true for the sake of argument, however, we do not find that the district court abused its discretion. The district court was concerned with Dr. Alexander's own characterization of non-adherence as comprising the top three of six explanations[6] for severe kidney rejections in previously-stable patients, and then his summary rejection of "non-adherence" as a cause of Huerta's kidney rejection in the face of contradictory evidence. Aug. 13, 2010 Op. at 8, 11-13. It was within the district court's discretion to find Dr. Alexander's testimony unreliable for this reason. *See Bitler*, 391 F.3d at 1124 ("[A]n inference to the best explanation for the cause of an accident must eliminate other possible sources as highly improbable, and must demonstrate that the cause identified is highly probable."); *see also Kumho Tire*, 526 U.S. at 152.

4. Testimony of Dr. Bruce Morgenstern[7]

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[6] A. (Dr. Alexander) "[T]here is almost nothing that will basically have the kidney go from .6 to a creatinine of 9, except nonadherence. And that is, for us, the main number, 1, 2, and 3, of the differential diagnosis when someone's kidney that's been stable for two years, no rejection prior to that time, suddenly fails.

Q. So nonadherence would be the first thing you would look at when somebody comes in with a spiking creatinine level; correct?

A. A very high creatinine.

Q. What's the second thing you look at?

A. Nonadherence.

Q. Well, I thought that was No.1.

A. It's No. 1, 2, and 3.

R., Vol. I at 80 (Deposition of Dr. Steven Alexander, Feb. 11, 2010).

[7] The parties and the district court differ in their spelling of Dr. Morgenstern's name and also spell it "Morganstern." For consistency, we will use the spelling of the title of

Dr. Bruce Morgenstern was prepared to testify that it was "highly probable" that the reason for Huerta's low tacrolimus levels in May of 2006 was the subpotency of BioScrip's tacrolimus suspension. Aug. 13, 2010 Op. at 9-10. Yet, the district court found that Dr. Morgenstern's testimony was based on the erroneous assumptions that the other physicians had definitively established that the tacrolimus suspension was subpotent when they had not, *id.* at 9, 11, and that other likely causes of Huerta's kidney rejection had been ruled out because of their absence from the medical records. *Id.* at 9.

Huerta argues that Dr. Morgenstern in fact reached his conclusions "given his experience as a pediatric nephrologist and statistical data," Aplt's Br. 21, citing only Dr. Morgenstern's ultimate causation testimony which does not mention any actual statistical data. *Id.* On this record and on our affirming the district court's exclusion of Dr. Wong's and Dr. Alexander's testimony, we are unconvinced that the district court made a clear error of judgment by excluding Dr. Morgenstern's testimony.

5. Testimony of Dr. Randall Tackett

Dr. Tackett was prepared to testify that "reduced levels of tacrolimus resulted in Huerta's kidney rejection and it was caused by a compounding error." Mem. Order and Op. Granting BioScrip's Motion to Exclude Proposed Testimony of Randall L. Tackett, PhD, August 18, 2010 ("Aug. 18, 2010 Op.") at 9. Dr. Tackett was also prepared to testify that "his 'guess' was that, when BioScrip pharmacists were compounding the April

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the appellant's *Daubert* motion, "Dr. Morgenstern." *See* R., Vol. I at 42.

or May 2006 suspension, either 'the wrong number of capsules were counted or emptied improperly.'" *Id.* (quoting R., Vol. I at 37).

The district court admitted Dr. Tackett's testimony relating sloppy pharmaceutical record-keeping with sloppy compounding. The district court also found that Dr. Tackett was qualified to testify regarding the most common type of compounding errors when capsules are used as an ingredient in the compound, and that BioScrip's compounding task was straightforward instead of complicated. *Id.* at 10. The district court, however, excluded Dr. Tackett's testimony on the standard of care for keeping pharmacy records, the actual potency or adequacy of the tacrolimus suspension dispensed to Huerta, and the cause of Blanca's kidney rejection being subpotent tacrolimus compounded by BioScrip.

Huerta argues that the district court erred in faulting Dr. Tackett's reliance on the findings of other experts as hearsay, and insists that Dr. Tackett "was able to conclude, based on all the evidence before him, from a pharmacological and toxicological standpoint . . . that the only cause not completely ruled out was a compounding error." Aplt's Br. 24-25. Huerta's arguments, however, fall short.

Huerta is correct to say that experts may offer opinions based on hearsay or other inadmissible evidence if experts in the field reasonably rely on such evidence in forming their opinions. *See* Fed. R. Evid. 703; *United States v. Posey*, 647 F.2d 1048, 1051 n.2 (10th Cir. 1981) ("If of a type reasonably relied upon by experts in the particular field in forming opinions or inferences upon the subject, the facts or data [in the particular case upon which an expert bases an opinion or inference] need not be admissible in

evidence."); *see also United States v. Mulder*, 273 F.3d 91, 102 (2d Cir. 2001). However, in this case, the district court also pointed out inconsistencies in Dr. Tackett's testimony, Aug. 18, 2010 Op. at 11-12, and Dr. Tackett's "dodg[ing] the issue" of Huerta's 2007 kidney rejection where non-compliance was suspected. *Id.* at 11. Huerta does not address either of these issues, which are alternative grounds upon which we could affirm the district court's order. *See Murrell v. Shalala*, 43 F.3d 1388, 1389 (10th Cir. 1994) (stating that an independently sufficient alternative basis for the district court's holding that is unchallenged forecloses success on appeal).

We note that this case presents difficult questions that a different district judge may have resolved differently. As this judge pointed out, all of Huerta's experts are well-qualified to testify on a variety of the underlying issues in this case. However, "when coupled with [the abuse of discretion] standard of review, *Daubert's* efforts to safeguard the reliability of science in the courtroom may produce a counter-intuitive effect: different courts relying on [] essentially the same science may reach different results." *Hollander*, 289 F.3d at 1206-07 (citing *Federal Judicial Center, Reference Manual on Scientific Evidence* 27 (2d ed. 2000)). For the reasons stated above, we find that the district court did not abuse its discretion by excluding the testimony of Dr. Wong, Dr. Alexander, Dr. Morgenstern, and Dr. Tackett as unreliable.

B. Whether the District Court Abused its Discretion in Admitting the Opinions of Bioscrip's Experts

Huerta next argues that the district court erred by admitting the testimony of two of BioScrip's experts. The district court granted summary judgment to BioScrip on the ground that BioScrip had admissible expert testimony that, more likely than not, factors other than subpotent tacrolimus[8] caused Huerta's kidney rejection. Aug. 19, 2010 Op. at 8-9. Because the district court held that Huerta did not have admissible expert testimony on causation, the district court also held that Huerta could not rebut the testimony of BioScrip's experts. *Id.* Thus, assuming without deciding that it was necessary for the district court to reach this issue given its exclusion of Huerta's experts' testimony, we address Huerta's arguments and reject them for the reasons stated below.

1. Dr. Chris Clardy

Huerta argues that the testimony of Dr. Chris Clardy should have been stricken because it was based on the wrong legal standard. According to Huerta, Dr. Clardy rendered the opinion that "'it is *not certain* that [Huerta's] low level [of tacrolimus] resulted from using an inadequate preparation of tacrolimus.'" Aplt's Br. at 34 (quoting R., Vol. I at 36) (emphasis from the appellant's brief). Because the proper standard under New Mexico law is whether something is true "to a reasonable degree of medical probability" rather than "certainty," Huerta argues that the district court abused its

[8] These causes included the change in Huerta's prescription from Cellcept to Imuran (a weaker immunosuppressant), Huerta's vomiting for three days before she was hospitalized and her creatinine levels were checked, that Huerta was vomiting for five days before her tacrolimus levels were checked, and the possibility of non-adherence to her medication regime. Aug. 19, 2010 Op. at 8 (citing R., Vol. II at 392-93).

discretion by admitting Dr. Clardy's testimony. *Id.* at 35 (quoting *Baca v. Bueno Foods*, 108 N.M. 98, 100 (N.M. App. 1988)).

When Huerta advanced these arguments before the district court, the district court found that they mischaracterized Dr. Clardy's opinion. The district court explained Dr. Clardy's actual proffer, citing Dr. Clardy's written report and his deposition testimony. Finding that Dr. Clardy's opinions were based upon correct legal standards and methodologies, the district court held that his opinions were admissible. Mem. Order and Op. Granding BioScrip's Mot. to Exclude Proposed Testimony of Chris Clardy and Lloyd Vernon Allen, August 9, 2010 ("Aug. 9, 2010 Op.") at 5.

Huerta's brief fails to address the district court's thorough analysis. Based on our review of the briefing, the record, and the district court's reasoning, we are unpersuaded that the district court abused its discretion in admitting Dr. Clardy's testimony.

2. Dr. Lloyd Vernon Allen

Huerta sought to exclude the testimony of Dr. Lloyd Vernon Allen on the ground that Dr. Allen's retention as an expert created a gross conflict of interest because of Huerta's retention also of Dr. Tom Kupiec. Huerta retained Dr. Kupiec as an expert witness in a prior action and also listed Dr. Kupiec in her initial disclosures in the instant action. Aplt's Br. 35-36. BioScrip subsequently retained Dr. Allen as an expert pharmacologist. Huerta argues that there is a close personal relationship between Dr. Allen and Dr. Kupiec, that they communicate frequently both in person and by e-mail, that they discussed this case briefly on at least one occasion, that Dr. Allen has worked

with Dr. Kupiec on a number of projects, and that Dr. Allen selects Dr. Kupiec's lab for quality assurance testing for pharmaceutical companies. *Id.* Thus, Huerta argues that there is an apparent conflict of interest between Dr. Allen and Dr. Kupiec and the failure to exclude Dr. Allen's testimony is an abuse of discretion. *Id.*

The district court found that Blanca's arguments mischaracterized Dr. Allen's testimony. The "frequent communication" between Dr. Allen and Dr. Kupiec was once every week or two, and at the time of Dr. Allen's deposition, the two doctors did not have any concurrent projects ongoing. Their "discussion" of the instant case was only a single instance when Dr. Allen mentioned to Dr. Kupiec that he had been retained in "a tacrolimus case." Dr. Kupiec mentioned that he had "a contact about that case," and immediately the two stopped talking about it. Aug. 9, 2010 Op. at 7-8. Ultimately, the district court found that "[Huerta] ha[s] failed to allege facts showing any conflict of interest, much less the 'gross conflict' that [she] contend[s] exists." *Id.* at 8.

Without citing a single case in support of her position, or identifying any error in the district court's reasoning, Huerta reiterates the arguments made before the district court and then insists that the district court abused its discretion. Based on the district court's thoughtful analysis and the facts found on the record before it (again, none of which Huerta's brief addresses), we are unpersuaded. *See also Habecker v. Town of Estes Park, Colo.*, 518 F.3d 1217, 1223 n.6 (10th Cir. 2008) (stating on appeal that the trial court erred without advancing reasoned argument as to the grounds for the appeal is

insufficient appellate argument). In sum, we find no error in the district judge's refusing to exclude Dr. Allen's testimony.

C. Whether the District Court Erred in Granting Summary Judgment in Favor of Bioscrip

We now turn to the district court's grant of summary judgment in favor of BioScrip, which we review de novo. *Garrison v. Gambro, Inc.*, 428 F.3d 933, 935 (10th Cir. 2005). We apply de novo review with application of the principle that "we view the evidence and draw reasonable inferences therefrom in the light most favorable to the nonmoving party." *Id.* Summary judgment "'necessarily implicates the substantive evidentiary standard of proof that would apply at the trial on the merits.'" *Burlington N. & Santa Fe Ry. Co. v. Grant*, 505 F.3d 1013, 1023 (10th Cir. 2007) (quoting *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 253 (1986)).

Huerta asserted claims for strict products liability, negligence, negligent misrepresentation, a violation of the New Mexico Unfair Trade Practices Act, breach of express and implied warranty, and for an award of punitive damages. In New Mexico, "a tort plaintiff must demonstrate the defendant's actions caused the plaintiff's injury." *Wilcox v. Homestake Mining Co.*, 619 F.3d 1165, 1166 (10th Cir. 2010). "[F]ailure of proof of an essential element renders all other facts immaterial." *Koch v. Koch Indus., Inc.*, 203 F.3d 1202, 1212 (10th Cir. 2000). When "the moving party does not bear the ultimate burden of persuasion at trial, it may satisfy its burden at the summary judgment stage by identifying a lack of evidence for the nonmovant on an essential element of the

nonmovant's claim." *Cassara v. DAC Serv., Inc.*, 276 F.3d 1210, 1212 (10th Cir. 2002) (internal quotation marks omitted). The burden then shifts to the opposing party to come forward with admissible evidence to create a genuine issue of material fact on that element. *See Bacchus Indus., Inc. v. Arvin Indus., Inc.*, 939 F.2d 887 891 (10th Cir. 1991).

Accordingly, after excluding Huerta's experts' causation testimony, the district court found that "BioScrip has demonstrated that there is no direct evidence that the tacrolimus suspension it compounded for Huerta was subpotent or otherwise defective, and that there were several other undisputed factors that could have contributed to Huerta's transplant rejection." Mem. Order and Op. Granting BioScrip's Motion for Summary Judgment, August 19, 2010 ("Aug. 19, 2010 Op.") at 7.

The district court held that the testimony of BioScrip's expert, Dr. Chris Clardy, was admissible, which we affirm as discussed above. Dr. Clardy was prepared to testify that while it was theoretically "possible" that BioScrip's tacrolimus suspension was subpotent and caused Huerta's kidney rejection, "there was a 75 to 80 percent 'probability' that the cause of Blanca's rejection was a combination of non-adherence or some other reason for insufficient levels of tacrolimus in her system other than subpotency, plus the change from Cellcept to Imuran." *Id.* at 8. With Dr. Clardy's testimony and "the undisputed fact that the other three patients taking BioScrip's tacrolimus suspension from the same batch as Blanca did not report any issues with the

tacrolimus BioScrip compounded," the district court found that "no reasonable jury could find that the tacrolimus was defective or caused Blanca's rejection." *Id.* at 8-9.

The district court then reasoned that "the continuing vitality of this case . . . depend[ed] upon a single issue: whether Plaintiffs [sic] have met their [sic] burden to come forward with sufficient, admissible, medical evidence to show that BioScrip compounded and dispensed subpotent tacrolimus that caused Blanca [sic] kidney-transplant rejection such that a reasonable jury could return a verdict in favor of the Plaintiffs [sic]." *Id.* at 7. Without admissible expert testimony to rebut Dr. Clardy's testimony on the issue of causation, the district court concluded that Huerta could not establish any of the following facts:

> (1) [that] the tacrolimus BioScrip marketed and dispensed was subpotent or defective; (2) [that] BioScrip's compounding of the tacrolimus suspension failed to meet the standard of care [to prove negligence]; (3) [that] BioScrip made any misrepresentations [sic] or concealed any information about the quality and efficacy of the tacrolimus it dispensed; (4) [that] BioScrip's tacrolimus was not fit for human consumption; (5) [that] Blanca's low levels of tacrolimus on May 17, 2006 were caused by BioScrip's marketing or dispensing of a defective product; or (6) [that] Blanca's transplant rejection and resulting injuries were caused by ingestion of subpotent tacrolimus.

Aug. 19, 2010 Op. at 9. Finding that Huerta did not meet her burden to demonstrate a genuine issue of material fact on causation, the district court granted summary judgment in BioScrip's favor. *Id.*

Huerta argues that genuine issues of material fact exist regarding causation, citing the testimony of her experts which we have held was within the district court's discretion to exclude. Aplt's Br. 26; Reply Br. 15. Aside from stating the elements of the strict

products liability tort in New Mexico, Huerta offers no argument as to how those elements have been met in this case, Aplt's Br. 30-31, and we decline to make them for her here. *See* Fed. R. App. P. 28(a)(9)(A) ("The appellant's brief must contain . . . appellant's contentions and the reasons for them, with citations to the authorities and parts of the record on which the appellant relies.").

On her negligence claim, Huerta argues that a jury is entitled to weigh the testimony given by the experts, and that contrary to BioScrip's arguments, she does not have to show that subpotent tacrolimus was *the* cause of her kidney rejection to avoid summary judgment. Aplt's Br. 31-32. Given that we hold that her experts' testimony was properly excluded, Huerta's first argument fails. Huerta's second argument mischaracterizes BioScrip's position. Nowhere does BioScrip argue that Huerta must show that subpotent tacrolimus must be the sole cause of her injury. Rather, BioScrip argues that given the variety of other potential causes of Huerta's kidney rejection, without her experts' testimony, Huerta could not show that more likely than not, the tacrolimus suspension dispensed was subpotent, that it was a but-for cause of Huerta's kidney rejection, or that it was a proximate cause of Huerta's kidney rejection. Aplee's Br. 52-54. To that end, the only case Huerta cites supports BioScrip's position: to sustain a negligence claim, "[p]laintiff . . . must prove that the act characterized as negligence *more probably than not* was *a contributing cause* of the injury." *Tafoya v. Seay Bros. Corp.*, 119 N.M. 350, 351 (N.M. 1995) (first emphasis added).

Next, Huerta summarily argues that BioScrip violated the New Mexico Unfair Trade Practices Act, Section 57-21-1 NMSA (1978), by selling subpotent medication and by failing to warn of the medication's subpotency. Aplt's Br. 32. As the district court held, however, Huerta cannot establish to a reasonable degree of medical probability that the BioScrip tacrolimus was subpotent without the testimony of her experts. Huerta's summary reliance on her experts' testimony to sustain her failure to warn and unfair trade practices claims, therefore fails. The same is true for her breach of express and implied warranty claims.

Because the district court properly granted summary judgment in favor of BioScrip, we need not address Huerta's claim for punitive damages.

III. Conclusion

For the foregoing reasons, we affirm the district court's granting of summary judgment in favor of BioScrip.

Entered for the Court

William J. Holloway, Jr.
Circuit Judge